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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
KER020/4-005CON

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on _____

Signature _____

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Application Number	Filed
09/899,372	July 2, 2001

First Named Inventor
Mark E. Van Dyke

Art Unit	Examiner
1651	Ghali, Isis A.D.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 60,000.
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

Erin Ator Thomson
Signature

Erin Ator Thomson
Typed or printed name

512.542.8762
Telephone number

July 6, 2009
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 1 forms are submitted.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Van Dyke, et al.	Group Art Unit: 1651
Serial No.: 09/899,372	Examiner: Isis A.D. Ghali
Filed: July 2, 2001	Atty. Dkt. No.: KER020/4-005CON
For: SOLUBLE KERATIN PEPTIDE	Confirmation No. 3035

PRE-APPEAL BRIEF REQUEST FOR REVIEW— ORAL HEARING REQUESTED

VIA EFS WEB MAIL STOP AF
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

This paper is submitted along with a Notice of Appeal in response to the Final Office Action ("the Action"), mailed on January 5, 2009, and the Advisory Action, mailed on May 1, 2009. The Commissioner is requested to consider this statement as a Petition for an Extension of Time under 37 C.F.R. § 1.136(a)(1) of three months to and including July 6, 2009 (July 5, 2009 was a Sunday). The fee for a three-month extension of time for a small entity, $525.00, is being paid electronically. If the authorization is inadvertently omitted, or should any additional fees be required for any reason relating to the enclosed materials, or should an overpayment be included herein, the Commissioner is authorized to deduct or credit said fees from or to Vinson & Elkins L.L.P. Deposit Account No. 22-0365/KER020/4-005CON.

A. Status of the Claims: Claims 55-65, 67, 68, and 93 are currently under examination.

B. Remarks

Applicants submit this request for Panel review. The Examiner has failed to consider Applicants' persuasive arguments with respect to the rejections based on 35 U.S.C. § 112, first paragraph for claims 55-56, 67, and 68. The Examiner has also failed to consider Applicants' persuasive arguments regarding the anticipation rejection of claims 55-65, 67, 68 and 93 under 35 U.S.C. § 102.

1. Rejection Under 35 USC § 112, first paragraph

The Action rejects claims 55-56, 67, and 68 under 112 first paragraph, as allegedly lacking enablement for the full scope of the claims. The Examiner's enablement rejection is based on a wholly improper understanding of what enablement is required for a composition claim. While the Examiner admits that Applicants' composition claims are enabled for at least one utility, the Examiner has maintained the rejection under the 1st paragraph of 112 based on the erroneous position that a ***composition*** claim must be enabled ***for every possible use***. The Examiner's rejection fails to that recognize that Applicants' have claimed compositions, and a composition claim that is enabled for at least one utility, as is admitted by the Action, is fully enabled. Nothing more is required.

The first paragraph of 35 U.S.C. § 112 requires the Specification to enable a person skilled in the art to make and use the claimed invention. The MPEP explains that, "if a statement of utility in the Specification contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are known and contemplated, 35 U.S.C. 112 is satisfied." MPEP § 2164.01(c). **Further, "if any use is enabled when multiple uses are disclosed, the application is enabling for the invention."** *Id.* Thus, when a claim is drawn to a composition, there is no legal requirement that the Specification describe or enable *every* possible use for that composition so long as at least one use is enabled.

A. The Examiner's enablement rejection completely ignores the established principal that "if *any* use is enabled when multiple uses are disclosed, the application is enabling for the invention."

The Examiner's rejection of the claims for lack of enablement is based the erroneous concept that the claims must be limited to only the uses described in the specification such as in therapeutic formulations, and further only in topical therapeutic formulations. Although the Specification describes therapeutic formulations that may be made with the claimed composition, the claimed composition is in no way limited to those described formulations. The invention of claim 55 is a powdered peptide composition. The composition is shown in the application to have useful bioactivity. *See* Para. [0021]-[0022]. The Examiner is incorrectly attempting to read a use limitation into the claims. In fact, the Specification discloses many uses for the composition that are known in the art. The Specification fully enables one of skill in the art to manufacture and use the claimed composition (1) in a formulation for topical administration via a cream, lotion, gel, hydrogel, or wound dressing to a human or animal subject; (2) to promote healing, repair, and cell growth in keratinous tissue generally; and (3) by orally administering the peptide to repair damaged keratinous tissue lining the GI tract. Para. [0021-0022].

B. The Examiner did not show that undue experimentation would be necessary.

The invention is fully enabled because at least one use, as a topical application, is enabled. But even if other uses must also be enabled, the Examiner did not meet her burden to show that *undue* experimentation would be necessary. MPEP 2164.01. The Examiner claimed that the composition is not enabled as to non-topical applications because it would require undue experimentation. Tellingly, the Examiner offered no explanation of what experimentation would be required, and why any such experimentation would be "undue," other than to say that trial and error experimentation would be required. Clearly, the Examiner has not met her "burden to establish a reasonable basis to question the enablement provided." MPEP 2164.04. Where no explanation is offered, there is simply no basis for a reasonable explanation. Moreover, even if some experimentation would be required to establish an appropriate dose of the claimed compositions, methods of placing proteins in an orally administered form is well known in the art and undue experimentation would not be required. See MPEP § 2164.01(c).

C. The Examiner's reliance on *In re Wands* is misplaced.

The Examiner relied on the factual inquiries as applied in *In re Wands,* 858 F.2d 731, 8 USPQ 2d 1400 (Fed Cir. 1988), to reach her conclusion that the claims are not enabled for the full scope of the claims. The criteria in *Wands* are not applicable to the present composition claim. For example, the question in *Wands* was whether the Specification taught one of skill how to make the antibodies that were used in the claimed method of immunoassay to detect hepatitis B surface antigen. *Wands*, 858 F.2d at 733. **Nowhere do Applicants find an issue of whether all possible uses of the antibodies were enabled.** In addition, in all the various later Federal Circuit cases that have cited *In re Wands*, Applicants cannot find a single one that applies the *Wand* factors to a composition claim to determine whether all possible uses of the composition are enabled by the Specification.

The issue here is not whether the Specification enables all possible uses of the compositions of peptides, but rather, the enablement of the peptide composition independent of adding it to a particular type of carrier. The Specification contains more than adequate description of how to obtain the peptide composition and also teaches how to use the composition to stimulate growth of useful cell types. Nothing more is required for enablement of the composition claims.

2. Rejection Under 35 USC § 102

The Examiner rejected claims 55-65, 67, 68, and 93 as anticipated by 5,276,138 ('138) because, according to the Examiner, the "'138 patent teaches a solubilized keratin powder from animal hair or wool" and teaches the steps "oxidation by hydrogen perioxide or peracetic acid; filtration, neutralization, precipitation of a powder; and washing the filtrate with solvent such as acetone,

methanol or ethanol." Applicants respectfully traverse the rejection because the present invention is based on the surprising result that the *filtrate* of oxidized hair contains biologically active peptides that can be collected by neutralizing the filtrate and precipitating out the peptides with a water-miscible organic solvent. Para. [0009]. The '138 patent teaches discarding the *filtrate* of oxidized hair and using the *precipitate* to recover much larger molecular weight proteins. Col. 4, lines 29-33; Example 1 at Col. 5-6.

The '138 reference describes a different process for obtaining the peptides than what is described in the present disclosure. The '138 patent teaches a process by oxidizing the hair, filtering it through a mesh (discarding the filtrate), precipitating with an acetic acid, filtering through a filter paper (discarding the filtrate), washing, drying, and pulverizing to obtain a powder. *See e.g.,* ('138) Example 1 at Col. 5-6. The present disclosure, on the other hand, teaches a different process; oxidizing the hair, filtering it (retaining the filtrate to collect the low molecular weight, water-soluble peptides), neutralizing the filtrate with a base, precipitating out the water-soluble peptides by mixing with a water-miscible organic solvent, filtering again and evaporating the precipitate. Para. [0014]-[0018]. Thus, the '138 reference teaches one skilled in the art to discard the objects of the present composition claims by disposing of the filtrate in the first filtration step. The '138 process contains no description of the water-soluble peptides found in the filtrate of the oxidized hair, nor does it teach or describe the surprising result that the filtrate of oxidized hair contains biologically useful peptides, which are the compositions claimed in the present disclosure.

The '138 reference describes different proteins than the claimed compositions. The '138 patent describes a composition containing high molecular weight, acid precipitable proteins. This subset of hair proteins is an acidic portion of the oxidized hair that is insoluble at low pH, and thus precipitates in acid. This protein subset has a much higher molecular weight than the peptides precipitated by ethanol at neutral pH as described in the present Specification (Para. [0018]) and claims. The present Specification discloses peptides of an average weight of 850 Daltons. Para. [0020]. In contrast, the '138 reference describes much larger peptides, the majority of which have a molecular weight of 25,000 to 67,000 Daltons. *See* ('138) Fig. 1.

The '138 reference actually teaches away from the present claims. The '138 reference does not suggest that any useful fraction of peptides can be precipitated from a soluble preparation (*i.e.,* isolated from the filtrate) of oxidized hair. The '138 does teach that a fraction can be precipitated by lowering the pH of the solution to below 4:

> As previously stated, the present invention relates also to the process for recovering the **solubilized product of the animal hairs**. . . .

> [T]he pH of the mixed system of the solution of the solubilized product of the animal hairs and the organic acid may be adjusted less than about 4.5, preferably 1-4. **If the pH of the mixed system is more than 4.5, the solubilized product of the animal hairs becomes hard to precipitate.** ('138) Col. 4, lines 29-33, 58-63 (emphasis added).

Thus, the '138 reference also teaches away from the present claims by teaching that the composition cannot be precipitated at pH above 4.5, and yet the claimed peptides are precipitated at neutral pH. Para. [0009]. Thus the claims are clearly distinguished from the disclosure of '138, both in the process of obtaining them and in their molecular weight, not just because of the process step alone, but because the different chemical characteristics of the two peptide compositions cause them to precipitate under different conditions.

Although the '138 patent discusses the use of a polar solvent such as alcohols, acetone and the like, this step is used to further purify the high molecular weight proteins that was the result of a previous acid precipitation and to "remove trace amounts of stinking components of low molecular weight, colored substances and the like contained in the solubilized product solution of the animal hairs," (Col. 5, line 24) and not to isolate a bioactive subfraction of peptides. The '138 can thus in no way be said to teach or suggest the present claims, and teaches away from the present claims by teaching precipitation from aqueous solution at low pH, and by teaching that only trace amounts of useless contaminants can be removed from the high molecular weight protein preparation by washing with aqueous solution of organic acids and/or volatile organic solvents.

C. Conclusion

In view of the comments above, Applicants respectfully request that the Panel grant an oral hearing and overturn the rejection of claims 55-56, 67, and 68 under section 112, first paragraph, and claims 55-65, 67, 68, and 93 under section 102, set forth in the Final Action, and that the Panel allow Applicants' claims.

Respectfully submitted,

Erin Ator Thomson

Erin Ator Thomson
Attorney for Applicants, Reg. No. 60,000

Vinson & Elkins LLP
First City Tower, 1001 Fannin, Suite 2500
Houston, TX 77002-6760
512.542.8446
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